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| EXAMINER |
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PRICE, NATHAN R

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/774,487 | Applicant(s) PAUL ET AL. | |
| | Examiner NATHAN R. PRICE | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 February 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/05/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. This office action is responsive to the preliminary amendment filed on March 1, 2004 and July 5, 2005. As directed by the amendment on March 1, 2004: claims 9-11, 18, and 32 have been amended, no claims have been cancelled, and no new claims have been added. Thus, claims 1-32 are presently pending in this application.

Drawings

2. The drawings are objected to because many elements in the drawings are unclear or difficult to discern to their hand-drawn nature. Particularly, the numbers used to identify elements in the drawings, and the various arrows, "X" markings, and dashed lines are difficult to discern. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are

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not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 5 is objected to because of the following informalities: “said a secondary vent” lacks antecedent basis, and “said a” is redundant. It is recommended to amend to “said at least one secondary vent”. Appropriate correction is required.

4. Claim 32 is objected to because of the following informalities: “mechanical housing, said battery housing, are” should be amended to “mechanical housing, and said battery housing are”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-8 and 12-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Blomquist et al. (US 20030163090).

7. Regarding claims 1, Blomquist et al. discloses an infusion device 10 (fig. 1-4), comprising: a casing comprising an external wall 14 (fig. 4) and a plurality of internal adjoining housings (battery chamber 114, cartridge chamber 80, and remaining

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chamber defined between for electronics and pump, see fig. 4), including a first housing 80 (fig. 4) enclosing a liquid reservoir 220 (see fig. 11; par. 0058) and a drive mechanism 88 (fig. 4; par. 0058); an electronics assembly (boards 450, 452, fig. 35; par. 0116) and a pump assembly 118 (fig. 4) provided in a second housing (remaining housing between 114 and 80, fig. 4) for controlling the drive mechanism to dispense the liquid from the reservoir according to a selected pattern; a battery (par. 0060) provided in a third housing 114 (fig. 4); and a primary vent 36 (fig. 2) provided for venting the infusion device to atmosphere (par. 0056), said primary vent comprising a hydrophobic barrier (par. 0056) allowing passage of gas therethrough while preventing passage of liquid therethrough (par. 0056); and at least one secondary vent 108 (fig. 4) provided between selected ones of said housings (par. 0059; between cartridge chamber 80 and interior of pump housing); said at least one secondary vent including a hydrophobic barrier (par. 0059) allowing passage of gas therethrough while preventing passage of liquid therethrough (par. 0059); said liquid reservoir contains insulin (par. 0003, pumps may be used to deliver insulin; par. 0112, this pump delivers insulin); said liquid reservoir defines a syringe (see fig. 10-11), comprising a generally tubular liquid storage section 202 (fig. 10) and a movable plunger 258 (fig. 9-10); said drive mechanism comprises a lead screw and a drive nut (par. 0064); said second housing is vented to atmosphere via said secondary vent (110 allows passage of gas between chamber 80 and interior of pump housing, par. 0059) and said first housing (first housing 80 having opening 28 when pump cap 16 is removed, par. 0054, 0059; fig. 1-4); means for a user to access said first housing (pump cap 16, fig. 1); means for a user to access said third

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housing (battery cap 24, fig. 1); said second housing is inaccessible by a user (there is no opening provided into the remaining chamber, see fig. 1); said casing is portable (via belt clip 850, fig. 36-37; par. 0136); said liquid reservoir is refillable (see par. 0072-0073; the reservoir is designed to be filled or refilled by a user); said liquid reservoir is replaceable (see par. 0079, reservoir is capable of being inserted and removed, and is capable of being replaced); said casing is configured to be concealed on a user (via attachment to a belt with belt clip 850, par. 0136; fig. 36-37); said secondary vent is provided between said second housing and said first housing (par. 0059); and said drive mechanism extends from said first housing to said second housing via an opening (par. 0059) comprising a seal (par. 0062).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Toner et al. (US 6562616).

10. Regarding claims 9-11, Blomquist discloses the apparatus as claimed except for said hydrophobic barriers comprise membranes, each said membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water and greater than or equal to approximately 10 psi. However, Toner et al. teaches hydrophobic membranes include membranes which are impermeable to water

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up to a certain pressure differential across the membrane (col. 13, ln. 66 - col. 14, ln. 8).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that said hydrophobic barriers comprise membranes, each membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water, as taught by Toner et al., since membrane materials having these characteristics can be easily obtained commercially or prepared using standard techniques (col. 14, ln. 6-8).

11. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a membrane with a pre-selected minimum water entry pressure of greater than or equal to 10 psi, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

12. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Lorenzen et al. (US 6770067).

13. Regarding claim 18, Blomquist discloses the apparatus as claimed except for said first, second, and third housings are hermetically sealed from one another against passage of liquid therebetween. However, Lorenzen et al. teaches hermetically sealing the different compartments within a pump housing (col. 6, ln. 34-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that said first, second, and third housings are hermetically sealed from one another against passage of liquid

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therebetween, as taught by Lorenzen et al., for the purpose of protecting the critical components of the pump from exposure to dangerous environmental conditions.

14. Claims 19-26, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg (US 6248093).

15. Regarding claims 19-26, 30, and 31, Blomquist discloses the apparatus as claimed (see elements identified in the rejections of claims 1-8 and 12-17 above), including a primary vent 36 (fig. 2) for venting the casing to the atmosphere, except for a plurality of primary vents for venting the casing to the atmosphere. However, Moberg teaches utilizing multiple primary vent ports in two different locations (col. 8, ln. 10-32 describe different possible locations for a vent port, and ln. 30-32 describe utilizing them in both locations at once). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist apparatus such that it comprises a plurality of primary vents, as taught by Moberg, for the purpose of further decreasing the chance of harmful differential pressures building up inside the device (col. 7, ln. 38-49).

16. Claims 27-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg, and further in view of Toner et al.

17. Regarding claims 27-29, Blomquist in view of Moberg discloses the apparatus as claimed except for said hydrophobic barriers comprise membranes, each said membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water and between about 10 psi and about 15 psi. However, Toner et al. teaches hydrophobic membranes include membranes which are

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impermeable to water up to a certain pressure differential across the membrane (col. 13, ln. 66 - col. 14, ln. 8). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Blomquist in view of Moberg apparatus such that said hydrophobic barriers comprise membranes, each membrane having a pre-selected minimum water entry pressure higher than a water pressure of a selected depth of water, as taught by Toner et al., since membrane materials having these characteristics can be easily obtained commercially or prepared using standard techniques (col. 14, ln. 6-8).

18. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to utilize a membrane with a pre-selected minimum water entry pressure between about 10 psi and about 15 psi, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

19. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blomquist in view of Moberg, and further in view of Lorenzen et al.

20. Regarding claim 32, Blomquist in view of Moberg discloses the apparatus as claimed except for said reservoir housing, said electronics and mechanical housing, and said battery housing are hermetically sealed from one another against passage of liquid therebetween. However, Lorenzen et al. teaches hermetically sealing the different compartments within a pump housing (col. 6, ln. 34-47). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the Blomquist in view of Moberg apparatus such that said reservoir housing, said electronics and mechanical housing, and said battery housing are hermetically sealed from one another against passage of liquid therebetween, as taught by Lorenzen et al., for the purpose of protecting the critical components of the pump from exposure to dangerous environmental conditions.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATHAN R. PRICE whose telephone number is (571)270-5421. The examiner can normally be reached on Monday-Thursday, 7:00 a.m. - 4:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/N. R. P./
Examiner, Art Unit 3763

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